REMARKS

Review and reconsideration of the Office Action of December 4, 2001 is respectfully requested in view of the above amendments and the following remarks.

Applicants apologize for the original claims, which were basically translations of European format claims, and accordingly difficult to examine. Applicants have now amended the claims to conform to US practice, so that the differences between the present invention and the prior art will be more readily apparent. Care has been taken not to introduce any new matter. Entry is respectfully requested.

Applicants appreciate the return of the initialed form PTO-1449 indicating that the references cited in the Information Disclosure Statement have been considered.

Applicants also appreciate the indication that the drawings have been approved.

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

Paragraph 1 - Claim Rejections - 35 USC §112

Claims 1-11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

Basically, the claims as originally presented for examination were in ``European form''. Applicants hereby present claims amended to US practice, taking care not to introduce any new matter. Entry is respectfully requested.

Paragraph 2 - Claim Rejections - 35 USC §102

Claims 1-6 and 8-11 are rejected under 35 U.S.C. §102(b) as being anticipated by Schaer (5,782,760). According to the Examiner, this reference teaches each and every element of the present claims, Applicants respectfully traverse.

Schaer teaches an over the wire electrophysiology **catheter**, with insulated wires bundled along the outside of the catheter and electrically connected to electrodes at the tip of the catheter. The catheter is designed for advancing through veins, and has a blunt tip (sharp edges are to be avoided), and may include a plastic tube covering. The inner lumen is obviously non-conductive.

The present invention, in contrast, is concerned with the task of providing a unipolar **cannula** for continuous anesthesia, which through simple construction and simple operation unites:

(a) the ability to place a catheter (the catheter itself not being a part of the present claims),

(b) the ability to administer anesthetic,

(c) no need for separate electrical conductors to supply electricity for electro-stimulation to the tip of the catheter, since the body of the catheter is used as a conductor, and

(d) the advantage of very precise electro-stimulation.

Where it was previously necessary to, e.g., simultaneously introduce a hose for anesthetic and a separate unipolar canula into a plastic cannula tube, the inventive unipolar **cannula** can be placed or located with the help of electrical nerve stimulation. The outer insulating covering of the cannula tube, which leaves only a very small, almost pinpoint area of the tip free (see original claim 7, now claim 18 and also new claim 23 -

exposed length about 1mm), makes possible an extraordinarily precise placement of the tip. The unipolar **cannula** can itself be used for the guided introduction of the **catheter**. The connection for electro-stimulation is introduced through the side of the body part and contacts the outside of the electrically conductive cannula tube. This manner of connection does not impede or constrict therewith the axial inlet opening of the body part. After the placement of the unipolar cannula with the help of electro-stimulation, the catheter can be introduced through the cannula tube, without any requirement that the position of the unipolar cannula must be changed or other measures be taken.

Preferably, a releasable or removeable connection is formed with the body part at the introduction opening, preferably a Luer-lock connection (claim 17). At this connection, an injection hose can be connected if desired, for injection of an initial or a short duration anesthetic. Likewise, a needle can be connected to the releasable connection, for injection of an anesthetic or also for fluids for aspiration for position control.

The possibility of using the body part both for the alternative connection of an injection hose or a needle as well as for introduction of the catheter makes the unipolar cannula extremely versatile. This versatility is achieved using an extremely simple and economical design. The manipulation of the unipolar cannula is likewise extremely simple, since the cannula can be employed without changing the position both for the injection or aspiration as well as for the introduction of the catheter. The axially aligned connection of a needle at the proximal body part makes possible also the carrying out of the nerve block with a one-hand technique.

Turning to Schaer, the catheter of Schaer differs in

structure for reasons of differences in function.

Schaer teaches blunt tip electrode designed to be advanced through cardiac veins up to the heart, in order to localize arrhythmias in the heart using a sensing electrode. The electrode is exposed over a large surface area in order to be able to be able to emit high frequency electrical energy, thereby to form large lesions, destroying tissue adjacent the blood vessel - without significantly damaging the blood vessel - to terminate signals causing arrhythmia.

In order for the catheter of Schaer to be capable of being pushed through the vein to the heart, the catheter must:

(1) have an appropriate length of from 80 to 300 cm (col. 7, lines 22-25), and

(2) be *flexible* so as to be able to follow the course of the vein.

For these reasons, the shaft of the intravascular device of Schaer is preferably formed of a plurality of individually insulated electrical conductors braided or wound into an elongated tubular member (col. 3, lines 5 - 10). Due to the flexibility and low strength of the catheter, it must be inserted with the aid of a guide wire (col. 3, lines 44 to 62). The distal tip, which forms the electrode, is not designed for or capable of use for ***piercing*** of tissue, rather is dull, so that the vein through which it is advanced is not damaged. The electrode tip is a separate metallic part, which extends from the distal end of the flexible catheter (col. 5, lines 11-39). The wires, which form the walls of the catheter, also serve as connection cables (21) at the proximal end (col. 5, lines 18-30).

In contrast to Schaer, present invention concerns a cannula adapted to be introduced into a nerve sheath, through which cannula then a flexible catheter can be inserted. Accordingly,

the cannula only has a length of about 25 to 200 mm (application, page 5, line 17). The cannula is a rigid tube, preferably of steel (page 5, lines 15-16). The cannula exhibits a sharp distal tip, so that it can pierce tissue. This tip can be facet cut (claim 8, Fig. 2) or be formed conically (claim 10, Fig. 3). The tip, which serves as an electrode, is not a separate part attached to the cannula tube, but is rather formed by the tip of the cannula tube itself. The electrical circuit (24, 26) are attached externally to the circumference of the cannula tube.

Accordingly, the present invention is structurally different from Schaer in that the cannula tube is a rigid tube having a tissue piercing tip as an integral feature thereof.

Further, the electrical connection occurs externally at the ***base*** of the cannula tube, not via wires wrapped or braided around the catheter and connected to the ***tip*** of a catheter as in Schaer.

For all these reasons the rejection can not be maintained. Withdrawal of the rejection is respectfully requested.

Paragraph 3 - Claim Rejections - 35 USC §103

Claim 7 is rejected under 35 U.S.C. §103(a) as being unpatentable over Schaer.

The Examiner had taken the position that Schaer discloses the invention substantially as claimed (in the original, European style claims). The Examiner acknowledges that Schaer does not disclose that the exposed end area of the distal tip of the cannula has a length of maximally 1mm.

In response, Applicants point out that Schaer teaches a cannula, not a catheter, that Schaer electrically connects at the tip not at the base, that Schaer teaches a blunt tip instrument not a tissue piercing instrument, and that Schaer does not teach an electrically conductive tubular body.

Accordingly, for all the reasons already presented under paragraph 3, withdrawal of the rejection is respectfully requested.

Early issuance of the Notice of Allowance is respectfully requested.

Respectfully submitted,

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Date: May 6, 2002

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing AMENDMENT A for U.S. Application No. 09/438,759 filed November 11, 1999, was deposited in first class U.S. mail, postage prepaid, addressed: Attn: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on May 6, 2002.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

Stephan A. Pendorf

VERSION WITH MARKINGS TO SHOW CHANGES MADE HEREBY ATTACHED

The Examiner is requested to accept the marked-up version as it is based on the previous version, which when modified as below, produces the clean version submitted with the current amendment.

IN THE CLAIMS:

Please cancel claims 1-11 in favor of the following replacement claims:

--12. A continuously conductive unipolar cannula for anesthesia, comprising:

an electrically conductive cannula tube (10) including a proximal end and a distal end, the distal end including a tip (14) and an exit opening (12, 44) in the area of the tip (14) dimensioned for passage of a catheter,

a body part (18) provided at the proximal end of the cannula tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the cannula tube (10) adapted for guiding a catheter for introduction into the proximal end of the cannula tube (10), and

a connector (22, 24, 26) electrically connected to the cannula tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said cannula tube (10) has an electrically insulated outer covering extending from the body part (18) out to the tip (14) and which leaves the tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the cannula tube (10).

13. A unipolar cannula according to Claim 12, wherein an electrical connection is formed between the electrical connector and cannula tube by an electrical contact pressed against the circumference of the cannula tube (10), to which contact a wire (24) of a multi-strand connector (26) is soldered.

14. A unipolar cannula according to Claim 13, wherein the wire (24) lies axially parallel against the cannula tube (10), and the multi-strand conductor (26) runs radially through the body part (18) towards the outside.

15. A unipolar cannula according to Claim 12, wherein the proximal end of the cannula tube (10) is provided co-axially in the body part (18), wherein a ring gap is formed between (a) the proximal end of the cannula tube (10) and the thereto connected electrically contacting connector (22, 24) and (b) an inner wall of the body part (18), and wherein said ring gap is filled with plastic (30).

16. A unipolar cannula according to Claim 12, wherein the inlet opening of the body part (18) decreases in diameter to form an inlet funnel oriented co-axially towards the proximal end of the cannula tube (10).

17. A unipolar cannula according to Claim 12, wherein the proximal end of the body part (18) is a Luer-lock connection (34).

18. A unipolar cannula according to Claim 12, wherein the electrically exposed end area (16) of the distal tip (14) of the cannula tube (10) has a length of maximally 1mm.

19. A unipolar cannula according Claim 12, wherein the distal tip (14) of the cannula tube (10) is a facet cut (12).

20. A unipolar cannula according to Claim 19, wherein the facet cut (12) is angled at an angle of approximately 45° to the axis of the cannula tube (10).

21. A unipolar cannula according to Claim 12, wherein the distal tip (14) of the cannula tube (10) is formed as a closed conically arched tip with an exit opening (44) provided along the side of the cannula tube proximally behind this tip.

22. A unipolar cannula according to Claim 21, wherein a ramp (46) is formed on the inside of the distal end of the cannula tube (10), adapted to guide a catheter toward the exit opening on the side of the cannula.

23. A continuously conductive unipolar cannula for anesthesia, comprising:

a steel electrically conductive cannula tube (10) including a proximal end and a distal end, the distal end including a sharp tip (14) and an exit opening (12, 44) in

the area of the tip (14) dimensioned for passage of a catheter,

a body part (18) provided at the proximal end of the cannula tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the cannula tube (10) for guiding a catheter for introduction into the proximal end of the cannula tube (10), and

a connector(22, 24, 26) electrically connected to the cannula tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said cannula tube (10) has an electrically insulated outer covering extending from the body part (18) out to the tip (14) and which leaves about 1mm of the tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the cannula tube (10).

24. A unipolar cannula as in claim 12, wherein said cannula tube tip is a facet cut tip.

25. A unipolar cannula as in claim 12, wherein said cannula tube tip is a Sprotte tip.--